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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,721	09/29/2003	Yuji Imaizumi	045070-5036	9270

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,721

Applicant(s)

IMAIZUMI ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 21-23, 25-31, 33, 34, 36, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-31, 33, 34, 36, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/06 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-31, 33, 34, 36, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 35 and 30 invoke 35 USC 112, sixth paragraph, with respect to the claimed "specifying means" and "selection means". In view of the instant specification it is not readily clear to one of ordinary skill in the art which of the disclosed structures provide the recited functions of the claims. As a result, the metes and bounds of the claims cannot be clearly determined. Note, page 23 of the instant specification implies that two different filter sets of a fluorescent microscope and image processing unit correspond to the recited "specifying means" and "selection means", however, it would appear that additional structure would be required to perform the functions recited in the instant claims, such as the control unit. As a result, it is not

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readily apparent to one of ordinary skill in the art which structures of the instant specification perform the function recited in the means plus function recitations of the instant claims (See MPEP 2181). The same hold true for the “detection means”, “calculation means” and “sorting means” recited in the dependent claims.

In claim 38, “said calculation means” and “said sorting means” lacks antecedent basis. Note claims 34, 31 and 30 are silent with respect to these additional recited means.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 25-31, 33, 34, 36, 38 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Yao et al.(US 2003/0100059).

The reference of Yao et al. discloses an intracellular measuring apparatus for measuring intracellular reactions wherein the apparatus includes a specifying means in which the intensity of the first light emitted from the specimen in accordance with the presence of a stated protein is detected to specify a noted region of the specimen based on the first light and a selection means in which the intensity of second light emitted from the specimen in accordance with intracellular reactions induced by the protein is detected, of the detected intensity of the second light, the

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intensity of the second light emitted from the noted region. Specifically Example 1 discloses the use of a real-time fluorescence imaging device that is capable of distinguishing a cell with the “stated protein” from cells that do not have the “stated protein” (See Figure 2c), that is specifying a first light (GFP emitted light) associated with transfected cells and identifying the transfected cells (a noted region). The imaging device also determines the intensity of a second light emitted by the transfected cells as evidenced by Figure 2c which plots the intensity of second light of transfected cells in addition of second light relative to non-transfected cells.

With respect to claim 25, the system disclosed by the reference of Yao et al. is structurally capable of measuring intercellular reactions in which a plurality of cells stand adherent to one another. The same holds true for distinguishing between a region wherein the protein is “in a higher proportion than a stated standard”. Also, the device is structurally capable of detecting emitted light from a cell within a group of adherent cells wherein cells that do not emit light are also present. If not, the device of Yao et al. would not be capable of distinguishing between transfected cells and non-transfected cells. Note page 23 of the instant specification defines the “specifying means” structure as a fluorescent microscope that can detect fluorescent protein (GFP) and an image processing unit. The reference of Yao et al. discloses both of these structures. The instant specification defines the “selecting means” as a fluorescent microscope that can detect membrane-potential-sensitive fluorescent dye and an image-processing unit. The reference of Yao et al. discloses both of these structures as well. As a result, the reference of Yao et al. structurally meets the instant claim language since the structures are the same and the device would be capable of being used in the manner intended by preamble of the claim.

The claims holds true for independent claim 30.

With respect to claims 26 and 31, the system inherently includes a chemical-substance introduction means for introducing substances which target the “stated protein”. If not, the norepinephrine and forskolin required of Example 1 could not have been added to the cell culture.

With respect to claims 27 and 33, the second light intensity is sampled over constant time as evidenced by the plot generated in Figure 2C.

With respect to claims 28 and 34, the system is structurally capable of detecting the intensity of a first light emitted by a fluorescent protein expressed together with the “stated protein” and a second light emitted from a fluorescent probe as evidenced by the GFP and Fura-2 of Example 1.

With respect to claims 29, 36 and 39, the real-time fluorescence-imaging device of Example 1 inherently includes the claimed detection means. If not, the plot of Figure 2C would not be capable of being generated. Specifically, the points when reagents were added relative to time.

With respect to claim 38, the device is structurally capable of distinguishing GFP positive cells relative the whole cell population and limiting the second light intensity to the GFP positive cells as evidenced by the GFP positive plot in Figure 2C.

Response to Arguments

3. With respect to the rejection of Claims 25-39 under 35 U.S.C. 102(e) as being anticipated by Yao et al.(US 2003/0100059), Applicants argue (See pages 17-18 of the response filed 6/9/2006) that the reference of Yao et al. does not teach or suggest at least the features of

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“specifying means” that detects first light emitted from the specimen that includes “noted region” where the cell(s) emitting the first light and cell(s) emitting no first light” are present, and the features of “selecting means” that detects second light emitted from the “noted region”. Applicants stress that the reference of Yao et al. only focuses on cells having the protein and detecting the second light emitted only from such cells.

In response, Applicants’ comments are not found to be persuasive because the Examiner is of the position that the device disclosed by the reference of Yao et al. is structurally the same as that of the instant claims. They both include optical excitation and detection systems for exciting and detecting the same wavelengths of light and employ image capture and processing devices. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant application, the reference of Yao et al. is structurally capable of performing the intended use recited in the instant claims. Applicants’ comments focus on how the method performed in the instant application is different from the method performed in the Yao et al. reference yet are silent as to how the instant device “structurally” defines over the device of Yao et al. Note, if clumps of cells (See Figures 3A and 3B of the instant application) were employed in the device of Yao et al., the device of Yao et al. would be capable of identifying the noted regions based on the first light and distinguishing between noted regions with the protein and without the protein based on the detected second light over time. Furthermore, in view of the indefiniteness of the instant claim language, it is not clear what, if any, structural differences exist between the instant invention and the device of the

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reference of Yao et al. other than the intended use of the device. Additionally note Figure 2B of the reference of Yao et al. which depicts "noted regions" of cells including the stated protein among cells which stand adherent to one another.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB